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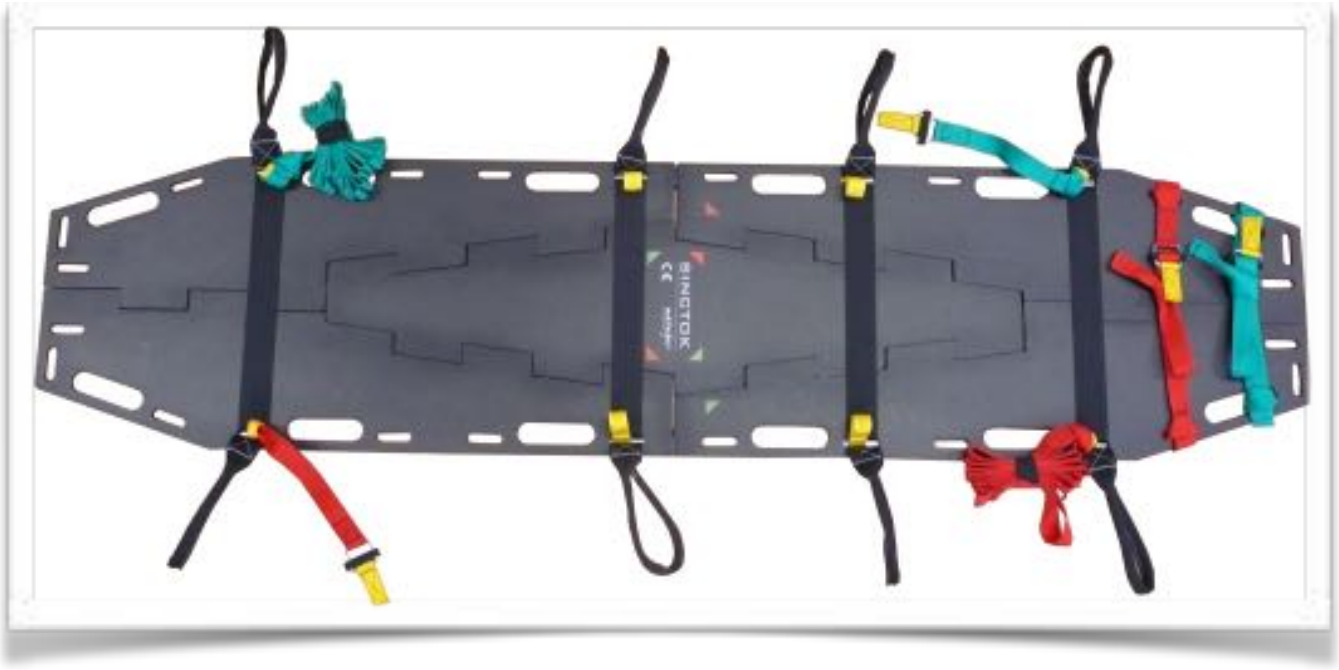
Use and maintenance manual

SINCTOK

(disassemblable spine board)



Five pieces, composite material,
modular, long spine board.

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Attention

This manual contains general information for the use, operation and maintenance of this product.
The instructions do not cover all possible applications and operations.
The safety and use of this product are at the discretion of the user.
Safety-related information is included for the user and ensures just the minimum level required to prevent accidents for operators and patients.
We recommend adequate training for the staff that will use this product before any actual application.

Keep this manual for future reference and in case the product is transferred to new users.
Additional copies may be requested from Northwall srl.

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Contents

1 Safety information	3
1.1 Safety warnings	3
1.2 Load limits	4
1.3 Risks of infection	4
1.4 Compatibility with accessories	4
1.5 Labels and safety symbols	4
2 Training and operator skills	4
2.1 Training	4
2.2 Operator skills	4
3 Description	5
3.1 Technical specifications	5
4 Instructions for use	6
4.1 How to assemble Sinctok	6
4.2 How to disassemble Sinctok	7
4.2 Use for rescue operations by lifting	7
4.3 Lifting	8
5 Maintenance	8
5.1 Storing Sinctok	8
5.2 Maintenance	8
5.3 Cleaning	8
5.4 Disinfection	8
6 Technical assistance	9
6.1 Service and training	9
7 Warranty limitations	9
8 Conformity	10
9 Training registration	11

1 Safety information

1.1 Safety warnings

This manual contains the following safety warnings:

- Untrained users may cause injury or get hurt. Only allow trained staff to operate Sinctok.
- Improper use of Sinctok may cause injury. Use Sinctok as described in this manual.
- Modifying Sinctok may cause injury and unpredictable operational problems. Do not modify or alter Sinctok in any way.
- Any damage or injury to Sinctok's structure could affect its performance and related safety. Frequently inspect Sinctok and do not use it in the event of excessive wear or damage.
- Do not leave the patient unattended for any reason while positioned on Sinctok. An operator must assist the patient during all rescue stages.
- If the safety fasteners for the patient are not secured, this may cause serious damage or injury.
- Applying Sinctok belts in a different way to the one specified in this manual may result in serious accidents.
- Any occasional helpers may damage Sinctok's structure. Control all operations when occasional helpers are present.
- Do not let occasional helpers carry out preparation manoeuvres on Sinctok or operations without the supervision of trained operators.
- Applying equipment on Sinctok incorrectly or combining it with tools that are not indicated in this manual may result in serious accidents.
- Unauthorized repairs performed by technicians or laboratories that are not authorized by Northwall srl shall make all warranties null and void and might endanger all operations when using Sinctok.

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1.2 Load limits

Comply with the maximum loads specified for each component of the system.
See the data sheet attached to this manual to check the loads and safety features.

1.3 Risks of infection

In order to reduce the risk of exposure to infectious diseases transmitted by blood, such as HIV-1 or hepatitis, while using Sinctok, carefully follow the disinfection and cleaning instructions specified in this manual.

1.4 Compatibility with accessories

Sinctok has been tested to be used for operations requiring accessories for immobilization, such as:

-Northwall head immobilizer system
-Northwall belt system

and other accessories specified by Northwall srl as compatible.
Apply immobilization systems to the patient that are in compliance with the technical specifications prescribed by current regulations.

1.5 Labels and safety symbols

The labels include important information that must be known to the user, and is described below.

Main label:

It shows the name of the product (Sinctok)
and production-related information concerning the serial number.
The main label is CE marked.

2 Training and operator skills

The operators authorized to use Sinctok must:

- know the procedures and precautions required when handling and moving patients;
- have the necessary skills for assisting patients;
- have understood the procedures described in this manual;
- have the necessary authorization and have carried out specific training with Sinctok.

2.1 Training

In order to complete adequate training, the following is required:

- carefully read this manual (contact your distributor, Northwall srl, for additional copies)
- train and practice with Sinctok and its accessories before using it in actual operations
- record training sessions performed with Sinctok (in this manual)

Untrained staff may cause or suffer serious injury.
Only allow appropriately trained staff to use Sinctok.

2.2 Operator skills

In order to use Sinctok in a specific environment, skills and knowledge are required which are not described but taken for granted in this manual.
Operators need to know how to act in a specific environment and ensure safety for themselves and the patient during all operations. They must also be able to use any other accessory provided.

The use of collaborators or occasional helpers for moving or lifting the patient should be limited to actual needs and in compliance with the general safety conditions.

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3 Description

Sinctok is a device for the immobilisation (long spinal board) and rescue of an injured patient with the aid of lifting accessories.

Sinctok is intended to protect an immobilised patient from a specific environment and transport him/her by lifting, using special handles or auxiliary systems which are compatible as specified, or by making Sinctok slide on even surfaces.

Sinctok is designed for the rescue of patients from confined industrial areas while ensuring all the handling precautions that are usually applied to injured patients.

Sinctok must only be used by adequately trained staff.
Contact Northwall srl to arrange specific training.

Northwall srl shall not be held liable for any damage caused to users or third parties due to improper use of the device.

Features

- 5 pieces carbon fiber and polyethylene board
- 12 lateral handles
- 28 rings for utility or immobilization belts
- 4 secure assembling belts with 2 immobilization loops each

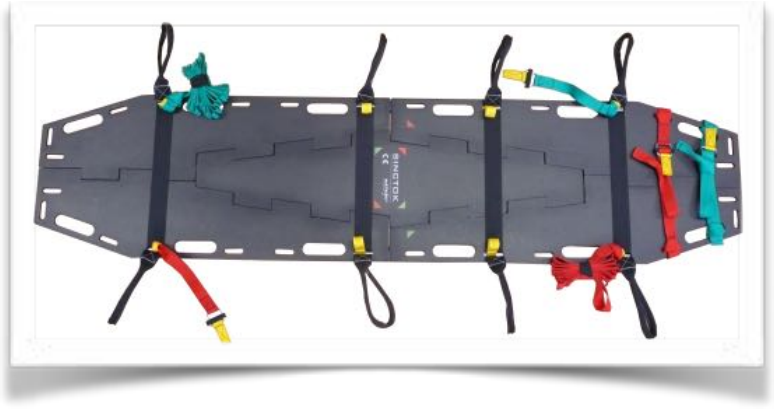
Modifying Sinctok's features may cause unpredictable reactions and serious injury to operators and the patient.
Do not modify or alter Sinctok's features in any way.

3.1 Technical specifications

Sizes and features
maximum length …… 1830 mm (72 in)
maximum width ……..……..…… 425 mm (16,7 in)
weight ……..……..…… 6,4 kg (14,1 lb)
maximum load……..……..…… 200 kg (441 lb)
maximum load per handle ……..……..…….. 50 kg (110 lb)

Materials used
external structure ……..…… carbon fiber, polyethylene
belts ……..…….. polypropylene, aluminum alloy
.
Tested accessories
belt system……..……..Northwall quick belts
head immobilizer system ……..…… Northwall NQH2I
rescue system ……..…… Tyromont HS-SACK

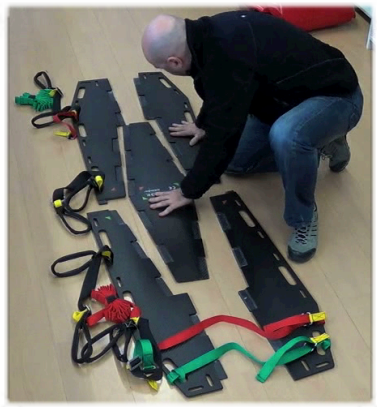
Check the load limits of the aids for the Sinctok system that are used for rescue operations.
Do not exceed the lowest load limit detected for the aids used for lifting.



(fig.1)

4 Instructions for use

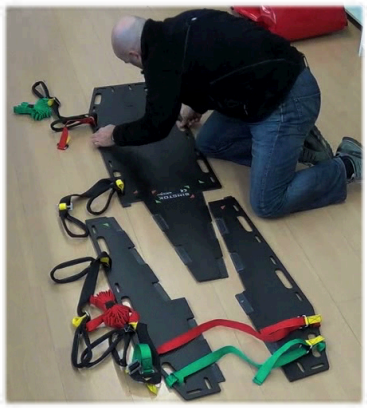
4.1 How to assemble Sinctok

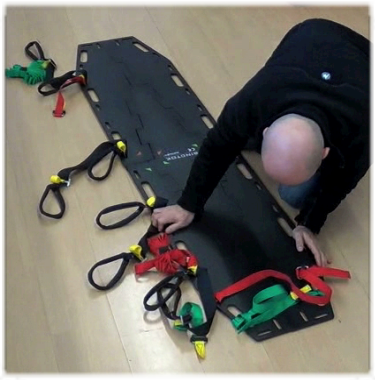


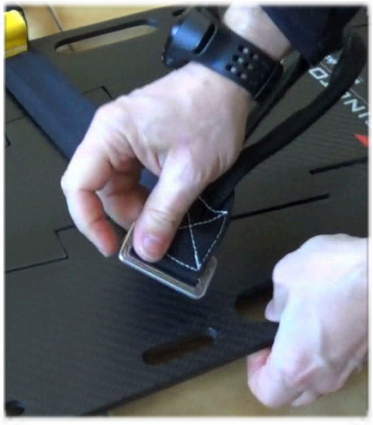
1.On a flat surface, dispose the parts in right position following the colored triangles on main central label

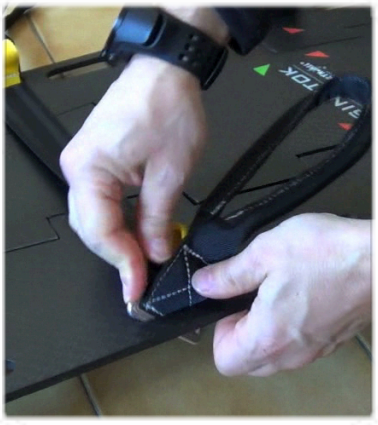
2.fit together the pieces

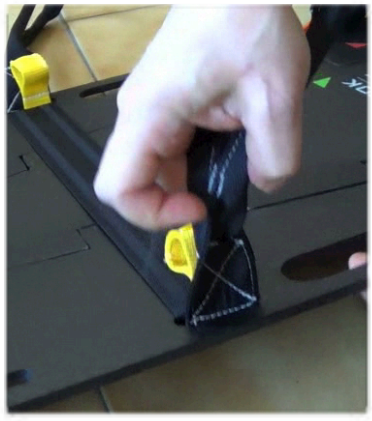
3.check that all the pieces fit together











4. insert the belt buckles with the handles into the corresponding holes in symmetric pieces
5. fasten and check the symmetric position of the handles
6. continue for all the four handle belts

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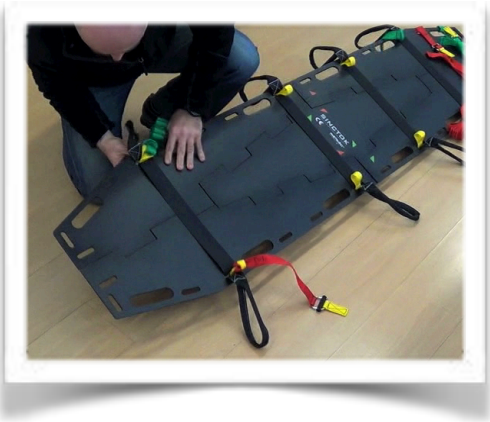
4.2 How to disassemble Sinctok



1.start to remove the buckles from one side

2.do the same for all the handle belts

3.pack up the stretcher and place it in the appropriate bag to minimize the size

4.2 Use for rescue operations by lifting

After loading the patient onto Sinctok while on the ground, follow the local health authority instructions to apply the fixation belts on the patient as shown in fig. 16,

(fig.16)

Secure the head immobiliser system (which is also able to secure a safety helmet for the patient if necessary)

An unattended patient may get injured. Do not leave the patient unattended. Assist him/her during all operations

Fixing the belts may vary depending on the size and conditions of the patient.

Before lifting or moving the patient using Sinctok, check that:

· the belts are fastened tightly and the patient is safe.
· all operators are in the correct position and the loops bearing the load do not exceed the limits specified in this manual

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4.3 Lifting

When lifting use only the appropriate loops, thus distributing the patient's weight on at least 6 loops.

Systems are to be applied to the loops, which ensure a secure grip in a specific operating environment.

Operators must be able to assess the number of helpers required to lift and move the patient according to his/her weight, thus limiting any danger for themselves and the patient, in compliance with current regulations.
Always use technical rescue gloves.

Untrained staff may cause or suffer serious injury. Only allow appropriately trained staff to use Sinctok.

Sinctok must only be used by adequately trained staff.

Contact Northwall srl to arrange specific training.

All the maneuvers described must be performed by experienced rescuers and after adequate and specific training.

The professionals who are authorized to use Sinctok in a specific environment must comply with the laws in force in each individual country.

Northwall srl shall not be held liable for any damage caused to rescuers or the patient due to improper use of Sinctok or if it is used by untrained or unauthorized staff.

Improper operation may cause serious accidents. Only use Sinctok as shown in this manual.

5 Maintenance

5.1 Storing Sinctok

We recommend storing Sinctok or the rescue kit containing it (e.g. Tyromont HS-SACK) ready for use.

In order to store Sinctok, we recommend deflating it using the low pressure valve and keeping it open during storage

5.2 Maintenance

IMPORTANT

The polyamide materials (belts and head immobiliser) and the materials Sinctok is made of, will deteriorate if exposed to prolonged direct sunlight and must not be directly exposed to sources of heat.

Sinctok must be stored in a cool, dry place protected from direct sunlight.

Sinctok must be inspected and decontaminated every time after use. If it is not used, it must be inspected at least once a month.

Sinctok should be inspected by persons authorised by Northwall srl at least every two years.

Sinctok and all its accessories can be used in climatic conditions with temperatures normally tolerated by humans.

5.3 Cleaning

Wash Sinctok with warm water and a mild detergent, then leave it to dry away from direct sunlight.
Make sure water or liquids do not enter Sinctok. Before each wash, make sure that the low pressure valve is closed and the safety lid is inserted and secured.

5.4 Disinfection

Use surface disinfectants approved by the local health authority.
Avoid ammonium-based disinfectants.
In the event of possible contamination due to immersion of the internal part of the device, please contact Northwall srl.

Improper maintenance may cause serious accidents.
Store Sinctok as described in this manual.

IMPORTANT
Disinfectants containing bleaches, phenols and iodine may cause damage to Sinctok's accessories.
Disinfect and clean using only products that do not contain these substances.
Maintenance table

	every use	when necessary	every month
disinfection	●		
cleaning		●	
inspection	●	●	●

6 Technical assistance
If you should require technical assistance for this product, as well as repairs and information, please contact Northwall srl.

6.1 Service and training
For any further information regarding its use and to arrange any necessary training, please contact Northwall srl.

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7 Warranty limitations

Northwall srl guarantees this product against any manufacturing defects in its materials for a period of two years.
This warranty applies when the product is used and maintained in compliance with the instructions provided in this manual.
Any misuse or improper maintenance shall make the warranty conditions null and void.
The warranty period takes effect from the day and the time the product is shipped by Northwall srl.
Shipping costs are not covered by this warranty.
Northwall shall not be held liable for any damage during shipping or any damage incurred while using this product.

If the product is partly or fully damaged, Northwall srl shall repair or replace the product or, if deemed necessary, shall refund its purchase price. The customer shall implicitly accept these warranty terms.

8 Conformity

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Langhirano, 2 ottobre 2013

Declaration of Conformity

PRODUCT IDENTIFICATION	MANUFACTURER
Commercial Name: SINCTOK *Model Number*: 5P	Northwall s.r.l. via Don Corchia, 8/e 43013 Langhirano (PR) Italia p.iva: 02663560346

CONFORMINTY ASSESMENT	ROUTE TO COMPLIACE	STANDARDS APPLIED
Device classification: CLASS I *Rule*: Long Spinal Board	93/42 EEC Council Directive	UNI EN 1865-1:2010

REGISTRATION INFORMATION		
Notify Body ID #: (not applicable for Class I medical devices)	*CE Certificate number:* (not applicable for Class I medical devices)	*Date CE Marking first applied:* 02.10.2013

Northwall s.r.l. decalres that the above mentioned products meet the provision of the Council Directive 93/42/EEC for Medical Devices.
All supporting documentation is retained at the premises of manufacturer.

COMPANY REPRESENTATIVE: Nicola Campani
TITLE: Vice President
DATE: 02.10.2013

SIGNATURE:

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CE

9 Training registration

Date	name of the operator	type of training	signature

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